REMARKS

I. Status of the Claims

Claims 39, 43, 49-51, 58, 62, 63, 69, 73 and 74 were pending and examined in the March 1, 2010 Office Action. With this Reply, claims 39, 43, and 49-51 are amended, claims 58, 62, 63, 69, 73 and 74 are newly cancelled, and claims 75-78 are newly added to more particularly point out and distinctly claim the invention. The claim amendments are made without prejudice or disclaimer and introduce no new matter. Support for the claim amendments is found at least at pages 10-22 of the specification as filed.

Claims 39, 43, 49-51 and 75-78 are presented for reconsideration.

II. Finality of the Office Action

The March 1, 2010 Office Action was made final, as discussed at page 16 of the Action. It is asserted therein that "[a]ll claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114." However, the March 1, 2010 Office Action includes a rejection of claims 39 and 49 under 35 U.S.C. 103(a) that was not made in the immediately prior final Office Action, dated July 22, 2009, although that obviousness rejection could have been made in that prior Action, since claim 39 and 49 were only amended to specify that Tupaia belangeri is the species that is infected. Certainly, if an obviousness rejection is entered relating to claims where Tupaia belangeri is infected, that same rejection should have been entered where any Tupaia species is infected. Thus, the rejection under 35 U.S.C. 103(a) was newly entered in the March 1, 2010 Office Action, where Applicants did not have the opportunity to address that rejection in the response to the July 22, 2009 Office Action. Since the March 1, 2010 includes a new rejection that was not in the immediately prior Office Action, the finality of the March 1, 2010 Office Action is improper. Accordingly, withdrawal of the finality of the March 1, 2010 Office Action and refund of the RCE fee accompanying this Reply is respectfully requested.

III. Rejections under 35 U.S.C. § 112

(a) Written Description

Claims 39, 43, 49-51, 58, 63, 69 and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicants request reconsideration and withdrawal of this rejection in light of the claim amendments and the following discussion.

The Action first asserts that "[t]he specification fails to provide a written description of a *Tupaia belangeri* infected with HCV, HIV-1 or HIV-2 and having a disease phenotype marked by inflammation, fibrosis, induced autoimmunity, or apoptosis, or any other disease phenotype, such that the infected animal would model the human infection and disease sequelae." Office Action at page 5. A similar objection is entered at page 8 of the Office Action, where it is asserted that "the instant specification provides **no** information with regard to disease phenotypes in *Tupaia belangeri* for human viral pathogens other than HBV." In response, Applicants note that the claims as amended that relate to HIV are claim 39 and claims dependent thereon. Claim 39 is fully described in the specification, since step c), "evaluating the effect of said potential therapeutic procedure on disease manifestations caused by said human viral pathogen in said infected animal" is fully described in the specification, e.g., at Example 3 at pp. 20-22, describing evaluation of HIV disease manifestations by measuring p24 in infected *Tupaia* peripheral blood lymphocytes. It is further noted that assays for other HIV disease manifestations are well known, for example tests for viral RNA levels in blood or in infected cells. In this regard, Applicants remind the Office that "[w]hat is conventional or well known to one of ordinary skill in the art need not be disclosed in detail." MPEP 2163 II.A.3.(a).

At page 7, bottom paragraph, the Action states, "there is no contemplation of carrying out the steps of the presently claimed method using a *Tupaia belangeri* infected with HIV-1 or HIV-2." However, the specification at page 9 provides such a disclosure in stating "[t]his aspect of the present invention provides a small animal model for infection by human retroviruses that can be used for screening therapeutic regimens for blocking viral replication in this host. It also

provides a means for identifying products and processes useful in therapetic treatment of viremia, including transient viremia and/or chronic viremia, and/or secondary manifestations that may be a result of infection by human retroviruses." The claims as filed also establish that these HIV-infected animal models (as recited in original claim 20) were contemplated "for developing or screening therapeutic, preventive or diagnostic products and procedures" (as recited in original claim 29. Thus, use of HIV-infected *Tupaia belangeri* for developing therapeutic procedures as claimed was clearly contemplated at the time of filing.

In light of the claim amendments and the above discussion, Applicants respectfully request withdrawal of the written description rejections under 35 U.S.C. 112, first paragraph.

(b) Enablement

Claims 39, 43, 49-51, 58, 63, 69 and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicants request reconsideration and withdrawal of this rejection in light of the claim amendments and the following discussion.

The Action first asserts that "[t]he specification fails to provide an enabling disclosure for the use of a *Tupaia belangeri* infected with HCV, HIV-1 or HIV-2 and having a disease phenotype marked by inflammation, fibrosis, induced autoimmunity, or apoptosis, or any other disease phenotype, such that the infected animal would model the human infection and disease sequelae." Office Action at page 11. In response, Applicants note that the claims as amended do not require inducing an HCV or HIV viral infection having a disease phenotype marked by inflammation, fibrosis, induced autoimmunity, or apoptosis. However, the specification is enabled for the claimed use of developing a therapeutic procedure in an HIV-infected *Tupaia belangeri* by evaluating the effect of a potential therapeutic procedure on disease manifestations, for example reducing viral load, since, e.g., Example 3 discloses a test for p24 production in infected cells. In this regard, since the specification describes successful infection of peripheral blood lymphocytes with HIV and maintenance of that infection for at least two weeks, the skilled artisan would understand that there is a reasonable expectation that a *Tupaia belangeri* could be

infected *in vivo*, such that a potential therapeutic procedure could be carried out with such an animal.

The Action also asserts at page 12 that "[t]he claims encompass genetically modified *Tupaia belangeri* animals, but the specification does not disclose any genetic modifications that could be made to render an individual *Tupaia belangeri* susceptible to infection by one of the human viral pathogens recited in the claims or to produce a model that more accurately reflects the disease manifestations observed in infected humans." In response, Applicants note that "[t]he presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984)" MPEP 2164.08(b). Here, the specification describes infection of *Tupaia belangeri* for the first time with HBV and HIV, and the skilled artisan would understand that such infected *Tupaia belangeri* could be used to develop a therapeutic procedure for those infections. One can always imagine inoperative embodiments for any claims. For example, the skilled artisan would understand that the instant claims are not enabled for practice on the surface of Mars or at the bottom of the ocean, but such inoperative embodiments is irrelevant to enablement of the claims as long as the skilled artisan could understand which embodiments are likely operative without undue experimentation. Thus, the skilled artisan would understand that the instant specification provides a new animal model for HBV and HIV which may not precisely mimic human infection with those viruses but is nonetheless useful, e.g., in testing potential therapeutic procedures that block replication or infection. As discussed at page 9 of the specification, these small animal models are cheaper and easier to maintain and have shorter lifespans than other HIV or HBV animal models, and thus provide a useful alternative to those models. As discussed above in relation to the presence of inoperative embodiments and the quote from MPEP 2164.08(b), the utility and enablement of the claimed invention is not negated by whether or not the claims are

enabled for a genetically engineered *Tupaia belangeri*, since such potentially inoperative embodiments would be understood as such by the skilled artisan.

IV. Rejections under 35 U.S.C. § 103

Claims 39 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xie et al. (1998, Virology 244:513-520). The Action asserts that Xie et al. disclose susceptibility of *Tupaia belangeri* to hepatitis C virus and thus makes obvious claims directed to developing a therapeutic procedure using a hepatitis C virus. Applicants request withdrawal of this rejection since none of the claims as amended are directed to the use of hepatitis C-infected animals.

V. Conclusion

In view of the foregoing remarks, Applicants respectfully request withdrawal of all rejections and passage of claims 39, 43, 49-51, and 75-78 to allowance.

No other fee or fees are believed due in connection with this paper. In the event that any fee or fees are due, however, the United States Patent and Trademark Office is hereby authorized to charge any such fee or fees to Deposit Account No. 05-1135, or to credit any overpayment thereto.

If a telephone conversation would further the prosecution of the present application, Applicants' undersigned attorney requests that he be contacted at the number provided below.

Respectfully submitted,

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